IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2974 1:20-md-02974-LMM
This document relates to: Pauline Rickard Melody Braxton Alisa Robere	:	CIVIL ACTION NOs.: 1:21-cv-03861-LMM [52] 1:22-cv-00490-LMM [48] 1:22-cv-01583-LMM [60]

ORDER

This multi-district litigation ("MDL") involves the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The matter is before the Court on a motion to exclude the opinions of Thomas Berry, Pharm.D., from evidence offered in defense against claims asserted by bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere (collectively, "Plaintiffs"). Upon due consideration, the Court enters the following Order.

I. BACKGROUND

Paragard is an IUD that is implanted into a patient's uterus by a healthcare provider. It is a T-shaped device that is made of polyethylene milled with barium sulfate and wrapped in copper. It is indicated for intrauterine contraception for up to 10 years. The T-shape is designed to collapse for insertion and removal. It is

supposed to be easy for a healthcare practitioner to remove the Paragard by gently pulling on attached threads.

Paragard has been approved and regulated by the FDA since 1984 without any significant design updates. Teva became the owner of the Paragard NDA in December 2008 and held it until the NDA was acquired by Cooper on November 1, 2017.[1]

Robere underwent placement of a Paragard in June 2011, Rickard had hers placed in May 2012, and Braxton had hers placed in November 2014. At the time Plaintiffs had their Paragards placed, there was nothing in the Warnings, Adverse Reactions, or Patient Information sections of the drug label about breakage, and each plaintiff expected for the removal of her Paragard to be simple and easy. But in each case—when Robere and Braxton had their Paragards removed in or around December 2019 and when Rickard had hers removed in August 2021—the Paragard was broken, and it was necessary for the plaintiff to have surgery to remove fragments of the Paragard.

Dr. Berry is a licensed pharmacist with a Pharm.D. and 33 years of pharmacy experience, including clinical practice and dispensing authority. He is currently a senior vice president at Eliquent Life Services, where he provides

[1] "Teva" or "Defendant" refers collectively to Defendants Teva Pharmaceuticals USA, Inc.; Teva Women's Health, LLC; and Teva Branded Pharmaceutical Products R&D, Inc. Defendant CooperSurgical, Inc. ("Cooper") was granted summary judgment of Plaintiff's claims in other Orders. See Dkt. Nos. [116, 137, 138].

strategic guidance and support to pharmaceutical and pharmacovigilance companies, including compliance strategies, due diligence, inspection readiness, corrective action plans, audits, and training. Earlier in his career, he worked for the FDA for 20 years, where he held titles such as Field Investigator, Compliance Officer, Director of Compliance, Acting Division Director of Bioresearch Monitoring, and National Program Expert.

In his expert report, Dr. Berry provides background on pharmacovigilance and outlines the respective responsibilities of manufacturers and the FDA in maintaining the pharmacovigilance process. See Expert Report of Thomas R. Berry, Pharm.D. ("Berry Rep.") at 8-22. Dr. Berry also offers the following opinions: (1) "[a] team of experts at the FDA reviewed Paragard and concluded that the benefit versus risk profile was acceptable for continued use by healthcare providers as a prescription drug and birth-control option for their patients"; (2) "from a pharmacovigilance perspective, Paragard labels from 2005 through Teva's tenure as the NDA holder reasonably warned healthcare providers and patients about risks of embedment and breakage; (3) alleged breakage concerns have not prevented prominent U.S. healthcare systems, such as the Cleveland Clinic, the Mayo Clinic, the Emory University School of Medicine, and Harvard Medical School from continuing to recommend Paragard; (4) breakage is an established and recognized risk for all FDA-approved hormonal and copper IUDs; and (5) the FDA's on-site post-marketing adverse drug experience

("PADE") inspections of Teva's pharmacovigilance programs and contractors did not document any objectionable conditions that resulted in FDA advisory or judicial action. Id. at 22-38. Dr. Berry additionally describes Teva's signal and adverse event processing, which he avers resulted in delivery of adverse event information to the FDA sufficient "to conduct their benefit versus risk analysis during their multiple reviews in 2018, 2022, and 2024," id. at 38-41; describes the FDA's PADE inspection program in place from 2008 to 2018, which he opines resulted in an inspection history "consistent with the profile for similar sized pharmaceutical firms and the evolution of pharmacovigilance programs over the last 20 years" and did not result in documentation of objectionable conditions, id. at 41-50; describes an external audit of Teva's companywide pharmacovigilance, id. at 50-55; and describes a Newly Identified Safety Signal ("NISS") study initiated by the FDA in September 2021, which, he opines, "did not reveal any new breakage related information that was not reasonably captured in the Paragard labels since 2005," id. at 55-58.

Plaintiffs do not dispute that Dr. Berry is generally qualified in postmarketing pharmacovigilance, in FDA inspections, and as a pharmacist. Dkt. No. [52] at 15.[2] They contend, however, that Dr. Berry's opinions lack foundation,

[2] Unless otherwise noted, record citations are to the documents filed in Rickard v. Teva Pharms. USA, Inc., Civ. Case No. 1:21-cv-03861-LMM (N.D. Ga.).

exceed his qualifications, and should therefore be excluded under Rule 702 of the Federal Rules of Evidence. Id.

The Court will first review the legal standards guiding adjudication of a motion to exclude evidence under Rule 702. It will then consider the parties' arguments as they apply to Dr. Berry's opinions.

II. LEGAL STANDARD

Federal Rule of Evidence 702 governs the admissibility of proposed expert evidence:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and,
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

The trial court, as the evidentiary gatekeeper, must determine that the testimony is "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Daubert v. Merrell Dow Pharm., 509 U.S. 579, 591 (1993) (quoting United States v. Downing, 753 F.2d 1224, 1242 (3d Cir. 1985)). The trial court must also "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an

expert in the relevant field." Kumho Tire Co. Ltd. v. Carmichael, 526 U.S. 137, 152 (1999).

The Eleventh Circuit has synthesized the existing rules into a three-part inquiry, instructing courts to consider whether: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998), reh'g and reh'g en banc denied, 172 F.3d 884 (1999).

With regard to the second factor, the Supreme Court explained in Daubert and its progeny that courts should serve a gatekeeping function in order to ensure the reliability of the methods employed by expert witnesses. 509 U.S. at 589. The Daubert inquiry specifically addresses the reliability of an expert's principles and methods. Daubert lists factors for courts to consider, including: (1) "whether [the theory or technique] can be (and has been) tested," (2) "whether the theory or technique has been subjected to peer review and publication," (3) "the known or potential rate of error," and (4) "general acceptance" of the theory in the field. Daubert, 509 U.S. at 593-94. Additional factors courts have used to assess reliability of expert methods include whether the opinion naturally flowed from

an expert's research or was developed specifically for litigation, and whether an expert has improperly extrapolated from a scientifically founded proposition to an unfounded conclusion. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1312, 1314, 1321 (11th Cir. 1999).

But "expert testimony that does not meet all or most of the Daubert factors may sometimes be admissible." United States v. Brown, 415 F.3d 1257, 1268 (11th Cir. 2005). Indeed, reliability is meant to be a flexible inquiry for district courts, allowing them to determine which factors may be relevant and to apply only those factors which the court sees fit. United States v. Frazier, 387 F.3d 1244, 1262 (11th Cir. 2004). "The burden of laying the proper foundation for the admission of the expert testimony is on the party offering the expert, and admissibility must be shown by a preponderance of the evidence." Allison, 184 F.3d at 1306. However, "the proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable." Id. at 1312.

The trial court has a great deal of flexibility in the inquiry into the reliability of an expert. Daubert, 509 U.S. at 595. This flexibility includes "latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability." Kumho Tire, 526 U.S. at 152.

"In the end, although rulings on admissibility under Daubert inherently require the court to conduct an exacting analysis of the proffered expert's methodology, it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." Quiet Tech. DC-8, Inc. v. Hurel Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003) (internal citations and quotations omitted). "Quite the contrary, 'vigorous cross-examination, presentation of contrary evidence and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.' " Id. (quoting Daubert, 509 U.S. at 596) (internal alteration omitted).

III. DISCUSSION

In its response to the motion to exclude Dr. Berry's testimony, Defendant clarifies that it offers Dr. Berry only for his opinions about pharmacovigilance. Dkt. No. [84]. Dr. Berry defines pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem" or, in other words, "adverse drug reaction monitoring, drug safety surveillance, side effect monitoring, spontaneous reporting, post-marketing surveillance or variations of these." Berry Rep. at 8.

Indeed, Dr. Berry appears to be well qualified as a pharmacovigilance investigator and auditor. Thus, to the extent that Defendant offers Dr. Berry to generally describe the pharmacovigilance, investigation, and audit processes, he

may testify on those issues. Based on that background and on his review of pharmacovigilance activities related to Teva and Paragard specifically, he also will not be precluded under Rule 702 from testifying about those processes.

However, the Court finds that Dr. Berry did not limit his opinions to pharmacovigilance. Nor did he demonstrate that he used reliable principles and methods or relied on sufficient facts or data for all of his opinions. Thus, after careful consideration of Dr. Berry's report, his deposition testimony, and Defendant's arguments, the Court finds that Defendant has not satisfied the Daubert inquiry as to Dr. Berry's other opinions.

The Court first considers the opinions Dr. Berry offers regarding the adequacy of the label. It then turns to Dr. Berry's opinions on Defendant's adverse-event tracking and reporting, his opinion that breakage is a known risk associated with all IUDs, and, finally, his reference to other healthcare systems' alleged opinions regarding Paragard's safety.

A. Testimony regarding adequacy of the label

As noted above, Dr. Berry opined that "[f]rom a pharmacovigilance perspective, Paragard labels from 2005 until Teva was no longer the applicant have reasonably warned healthcare providers, as the learned intermediary, and patients about Paragard embedment and breakage." Berry Rep. at 27. That is not an opinion that Dr. Berry is qualified to provide.

Defendant clarifies that Dr. Berry looked at the label from a pharmacovigilance standpoint. Dkt. No. [84] at 7-8. According to Dr. Berry, "[W]e look at the label, and if [an adverse event is] in the label, it's considered to be an expected event. It doesn't matter where in the label it is, if it's anywhere in the label." Berry Dep. at 132.

The Court is at a loss to see how this opinion would be helpful to the jury in determining whether the label provided sufficient breakage warnings. In the pharmacovigilance context, "unexpected" is a term of art related to post-marketing reporting requirements. See generally 21 C.F.R. § 314.80. Whether the label signaled from a pharmacovigilance standpoint that breakage was an "expected event" is, at best, tangential: here, the question is not whether the label mentioned breakage at all but instead whether the disclosures on the label were adequate to fully apprise a reasonable physician of the risk of Paragard breakage. See Dkt. No. [149] at 7-11. Dr. Berry's opinion that breakage was not an "unexpected adverse drug experience" in the context of § 314.80(a) sheds no light on that question. Defendant also does not demonstrate why, as a pharmacist and pharmacovigilance expert, Dr. Berry would otherwise be qualified to opine on whether the label was adequate to warn a reasonable physician of the risk of Paragard breakage.

Dr. Berry therefore will not be permitted to testify as to whether the Paragard label carried an adequate breakage warning.

B. Tracking and reporting of adverse events

In its response to the motion to exclude Dr. Berry's testimony, Defendant clarifies that it intends for Dr. Berry's pharmacovigilance opinions to show that "the breakage warnings reasonably reflect the safety information about Paragard that is available through the pharmacovigilance process." Dkt. No. [84] at 7. However, after carefully reading Dr. Berry's expert report and his deposition transcript, the Court agrees with Plaintiffs that Defendant has failed to show that Dr. Berry used reliable methods or considered sufficient facts or data to determine that all of the adverse events or drug-related problems were accurately captured, reported to the FDA, and reflected in the label.

The only reference to methodology in Dr. Berry's report appears in the summary of his opinions, where he states,

> The methodology of my opinions is primarily based on an objective consideration of the FDA benefit versus risk drug approval process, the adequacy of the label for ensuring healthcare providers as learned intermediaries are appropriately informed of the benefit versus risk profile, the veracity of post-market information, and FDA's post-market analysis, specifically the FDA Clinical Review of Newly Identified Safety Signal.

Berry Rep. at 23. He additionally states that his review was facilitated by his "education, training, and experience at FDA relating to pharmacovigilance and as a clinical pharmacist relating to drug safety and efficacy." Id.

This is problematic for several reasons. First, as Plaintiffs point out, this is not a methodology. Instead, it is a simple recitation of Dr. Berry's opinions and some of the documents he relied on.

Second, as discussed above, so far as Dr. Berry's "methodology" relies on his opinion that the 2005 label was adequate to inform a reasonable physician of the risk of Paragard breakage, that was not an opinion that Dr. Berry was qualified to provide. See supra Part III.A. Thus, this basis for Dr. Berry's opinions is itself without foundation.

Third, Dr. Berry has not explained the process by which he made his "objective consideration" of the FDA risk/benefit drug approval process or "the veracity" of post-market information and the FDA post-market analyses. There is no explanation in the expert report of how he did this, and his assurances in his deposition that he conducted his review as he would have conducted an inspection as an employee of the FDA are not enough. See McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1244 (11th Cir. 2005) ("The expert's assurances that he has utilized generally accepted scientific methodology are insufficient." (cleaned up)). Moreover, Dr. Berry could not identify what documents he relied upon in formulating his opinions: while he testified that he reviewed adverse event reports, PADERs, and FDA reports that were given to him by the law firm, as well as additional adverse event documents and other records he requested based on his review, he could not list those documents, articulate how they were selected,

or describe the concerns that triggered his requests for additional documents. See Berry Dep. at 65-68, 70-75, 89, 91-92, 144-47, 182-83, 187.

The Court also finds it notable that nowhere in his expert report did Dr. Berry describe his efforts to suss out adverse events that Defendant might have missed or miscoded. Compounding this, Dr. Berry appears to have ignored or glossed over myriad documents suggesting that Teva's recordkeeping was substandard and that its pharmacovigilance system was riddled with errors. See, e.g., Deposition of James Keller at 164-65 (former Cooper employee's testimony regarding concerns with Teva's recordkeeping and FDA reporting); Dkt. No. [99-1] (2010 Establishment Inspection Report identifying inadequate complaint procedures); Dkt. No. [99-3] 2016 FDA inspection report noting that Teva had not developed written procedures for the receipt and reporting to the FDA of post-marketing adverse drug experiences); Dkt. No. [99-4] (summary of May 2011 audit report identifying numerous pharmacovigilance issues).

In sum, Dr. Berry's report does not demonstrate methodology or analysis sufficient to assure the Court that he critically reviewed Defendant's processes and data to ensure that there were no missing or obscured adverse events. Consequently, Dr. Berry will not be permitted to testify that Defendant properly collected adverse events, that Defendant properly communicated adverse events to the FDA, or that, as a result, "the breakage warnings reasonably reflect the

safety information about Paragard that is available through the pharmacovigilance process."

C. Breakage as an established risk of IUD use

Dr. Berry's opinion that device breakage is an established and recognized risk for all FDA-approved hormonal and copper IUDs is due to be excluded for similar reasons. Simply put, the opinion assumes, without establishing a foundation, that the FDA had been properly apprised of the type, the frequency, and the severity of Paragard breakage. Furthermore, the evidence Dr. Berry relies on for the opinion is dated years after Plaintiffs had their Paragards placed, and it thus has little to no relevance to Plaintiffs' claims. Dr. Berry therefore will not be permitted to testify that device breakage is an established and recognized risk for all FDA hormonal and copper intrauterine devices.

D. Paragard use by certain prominent U.S. healthcare systems

Dr. Berry's opinion that alleged breakage concerns have not prevented certain prominent U.S. healthcare systems from continuing to recommend Paragard suffers from similar problems. There is no showing the Dr. Berry has expertise in how healthcare systems evaluate the use of any prescription drug. His sources are also questionable at best, as he simply cites to the public facing websites of several healthcare systems that he subjectively thought were representative and reputable. Accordingly, Dr. Berry will also be precluded from testifying about this opinion.

IV. CONCLUSION

Plaintiffs' motion to exclude Thomas Berry from offering evidence in the bellwether cases is **GRANTED IN PART AND DENIED IN PART**, as set out above.

IT IS SO ORDERED this 16th day of January, 2026.

Leigh Martin May
Chief United States District Judge